Approved for use through 10/31/2002 OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Form 1449/A/PTO

JAN 0 7 2004

Sheet 1

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary of 4

Con	nplete if Known
Application Number	09/653,406
Filing Date	09/01/2000
First Named Inventor	Jennifer L. West
Group Art Unit	1615
Examiner Name	Di Nola Baron, Liliana
Attorney Docket Number	47400-0100 (47400-252658)

Examiner	Cite No.1	U.S. Patent D	Nocument  Kind Code <sup>2</sup> (If known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
Salues		4,526,938		Churchill et al.	07-02-1985	
281-07	2	4,716,203		Casey et al.	12-29-1987	
_	3	4,741,337		Smith et al.	05-03-1988	
_	4	4,957,744		della Valle et al.	09-18-1990	
	5	4,987,744		Handley et al.	01-29-1991	
+	6	5,410,016		Hubbell et al.	04-25-1995	
	7	5,508,317		Müller	04-16-1996	
	8	5,632,981		Saavedra et al.	05-27-1997	
-	9	5,665,840		Pöhlmann et al.	09-09-1997	
-	10	5,807,927		Stockinger et al.	09-15-1998	
_	11	5,849,839		Hubbell et al.	12-15-1998	
-	12	5,849,841		Mühlebach et al.	12-15-1998	
	13	5,900,433		Igo et al.	05-04-1999	
	14	5,910,316		Keefer et al.	06-08-1999	
	15	5,932,674		Müller	08-03-1999	
	16	5,939,489		Müller	08-17-1999	
<del>-  -</del>	17	6,011,077		Müller	01-04-2000	
	18	6,299,604	B1	Ragheb et al.	10-09-2001	
1	19	6,262,206		Nesvadba et al.	07-17-2001	
					-	

				FORE	IGN PATENT DOCUMEN	TS		
Examiner Initials	Cite No.	Office <sup>3</sup>	Foreign Patent Doc Number <sup>4</sup>	Kind Code <sup>3</sup> (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	т <sup>6</sup>
Sones	20	PCT JO	WO 96/32136		The United States of Americaet al.	10-17-1996		
	21	PCT	WO96/15797		The United States of America represented by the Secretary, Dept. of Health and Human Services	05-30-1996		
4	22	PCT	WO 01/15738		Rice University	03-08-2001		

Examiner Signature	262 hole Para	Date Considered	3/17/04

'Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the weather (WIPO Standard ST.3). <sup>4</sup>For Japanese patent document, the indication of the year of the reign of the Emperor must precede the set of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>3</sup>Applicant is to place a check mark here if English language translation is attached.

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary

Sheet 2 of 4

· · · · · · · · · · · · · · · · · · ·	
Filing Date	09/01/2000
First Named Inventor	Jennifer L. West
Group Art Unit	1615
Examiner Name	Di Nola Baron, Liliana
Attorney Docket Number	47400-0100 (47400-252658)

		OTHER INFORMATION - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	23	BOHL et al., "Nitric oxide-generating polymers reduce platelet adhesion and smooth muscle cell proliferation", Biomaterials,	
Sono?		2000, 2273-2278, Vol. 21	
	24	BOHL et al., "Nitric Oxide-Releasing Materials for the Prevention of Thrombosis and Restenosis", Proceed. Int'l. Sym. Control.	T
		Rel. Bioact. Mater., 2000, 143-144, Vol. 27	
	25	BOHL et al., "Nitric Oxide Producing Materials: A Potential Therapy for Thrombosis and Restenosis", Proceed. Int'l. Sym.	
		Control. Rel. Bioact. Mater., 1999, 56-57, Vol. 26	
	26	BOHL et al., "Nitric Oxide-Releasing Hydrogels for the Prevention of Thrombosis and Restenosis", Circulation, Oct. 31, 2000;	1
		II.734, Vol. 102, No. 18 (Abstract only)	
.	27	COHN et al, "Biodegradable PEO/PLA block polymers", J. Biomed. Mater. Res., 1988, 993-1009, Vol. 22	
	28	COOKE et al., "Antiatherogenic Effects of L-Arginine in the Hypercholesterolemic Rabbit", J. Clin. Invest., 1992, 1168-1172,	-
1		Vol. 90	
1	29	DE GRAAF et al., "Nitric Oxide Functions as an Inhibitor of Platelet Adhesion Under Flow Conditions", Circulation, 1992, 2284-	<del>                                     </del>
-		2290, Vol. 85	
	30	DE MEYER et al., "Effect of Nitric Oxide Donors on Neointima Formation and Vascular Reactivity in the Collared Carotid Artery	
		of Rabbits", J. Cardiovasc. Res., 1995, 272-279, Vol. 26	
	31	DIODATI et al., "Complexes of Nitric Oxide with Nucleophiles as Agents for the Controlled Biological Release of Nitric Oxide:	
		Hemodynamic Effect in the Rabbit*, J. Cardiovasc. Pharm., 1993, 287-292, Vol. 22	
	32	DIODATI et al., "Complexes of Nitric Oxide with Nucleophlles as Agents for the Controlled Biological Release of Nitric Oxide:	
		Antiplatelet Effect", Throm. Haem., 1993, 654-658, 1993	
	33	GARG et al., "Nitric Oxide-Generating Vasodilators and 8-Bromo Cyclic Guanosine Monophosphate Inhibit Mitogenesis and	
		Proliferation of Cultured Rat Vascular Smooth Muscle Cells", J. Clin. Invest., 1989, 1774-1777, Vol. 83	
	34	GREENHALGH, "The Role of Growth Factors in Wound Healing", J. Trauma, 1996, 159-167, Vol. 41	
	35	HELLER et al., "Nitric Oxide Inhibits Proliferation of Human Endothelial Cells via a Mechanism Independent of cGMP",	
1		Atherosclerosis, 1999, 49-57, Vol. 144	
-	36	HERN et al., "Incorporation of Adhesion Peptides into Nonadhesive Hydrogels Useful for Tissue Resurfacing", J. Biomed.	$\vdash \dashv$
4	- 1	Mater. Res., 1998, 266-276, Vol. 39	

<u> </u>			
Examiner Signature	Lez nole Baro	Date 3/17/04	RECEIVED

PTC/SB/08B (08-00)
Approved for use through 10/31/2002 OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Sheet 3

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary

of 4

Cor	nplete if Known
Application Number	09/653,406
Filing Date	09/01/2000
First Named Inventor	Jennifer L. West
Group Art Unit	1615
Examiner Name	Di Nola Baron, Liliana
Attorney Docket Number	47400-0100 (47400-252658)

		OTHER INFORMATION - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	37	HOLLAND et al., "Polymers for Biodegradable Medical Devices. 1. The Potential of Polyesters as Controlled Macromolecular	
Lenes		Release Systems, 1986, 155-180, Vol. 4	
1	38	IGNARRO et al., "Mechanism of Vascular Smooth Muscle Relaxation by Organic Nitrates, Nitroprusside and Nitric	
		Oxide: Evidence for the Involvement of S-Nitrosothiols as Active Intermediates", J. Pharmacol. Exp. Ther., 1981, 739-749, Vol.	
		218	
	39	KWON et al., "Inhibition of Tumor Cell Ribonucleotide Reductase by Macrophage-derived Nitric Oxide", J. Exp. Med., 1991,	
		761-767, Vol. 174	
	40	LEFER et al., "Antineutrophil and Myocardial Protecting Actions of a Novel Nitric Oxide Donor After Acute Myocardial Ischemia	
.		and Reperfusion in Dogs", Circulation, 1993, 2337-2350, Vol. 88	
	41	LEGRAND et al., "Preclinical Promise of Becaplermin (rhPDGF-BB) in Wound Healing", Am. J. Surg., 1998, 48S-54S, Vol 176	
•	42	LEPOIVRE et al., "Inactivation of Ribonucleotide Reductase by Nitric Oxide", Biochem. Biophys. Res. Comm., 1991, 442-448,	
		Vol. 179	
	43	MANN et al., "Tethered-TGF-β Increases Extracellular Matrix Production of Vascular Smooth Muscle Cells", Biomaterials,	
		2001, 439-444, Vol. 22	
	44	MARAGOS et al., "Nitric Oxide/Nucleophile Complexes Inhibit the in Vitro Proliferation of A375 Melanoma Cells via Nitric	
		Oxide Release", Cancer Res., 1993, 564-568, Vol. 53	
	45	MARTINEZ-DE JESUS et al., "Randomized Single-Blind Trial of Topical Ketanserin for Healing Acceleration of Diabetic Foot	
ļ		Ulcers", Arch. Med. Res., 1997, 95-99, Vol. Spring 28 (1) (Abstract only)	
	46	MATHEWS et al., "Biological Activity of S-Nitrosothiols: The Role of Nitric Oxide", J. Pharmacol. Exp. Therap., 1993, 1529-	
		1537, Vol. 267	
	47	MORO et al., "cGMP Mediates the Vascular and Platelet Actions of Nitric Oxide: Confirmation Using an Inhibitor of the Soluble	
		Guanylyl Cyclase*, Proc. Natl. Acad. Sci. USA, 1996, 1480-1485, Vol. 93	
	48	RODOMSKI et al., *Comparative Pharmacology of Endothelium-Derived Relaxing Factor, Nitric Oxide and Prostacyclin in	
		Platelets", Br. J. Pharmacol., 1987, 181-187, Vol. 92	
-+	49	SARKAR et al., "Nitric Oxide Inhibition of Endothelial Cell Mitogenesis and Proliferation", Surgery, 1995, 274-279, Vol. 118	

Date 3/17/04 La nole Bara RECEIVED Examiner Signature Considered

Substitute for Form 1449/A/PTO **Application Number** 09/653,406 Filing Date 09/01/2000 INFORMATION DISCLOSURE First Named Inventor Jennifer L. West STATEMENT BY APPLICANT **Group Art Unit** 1615 (use as many sheets as necessary **Examiner Name** Di Nola Baron, Liliana 47400-0100 (47400-252658) Attorney Docket Number of 4 Sheet 4 OTHER INFORMATION - NON PATENT LITERATURE DOCUMENTS SAWHNEY et al., "Rapidly Degraded Terpolymers of dl-Lactide, Glycolide, and ε-Caprolactone with Increased Hydrophilicity 50 by Copolymerization with Polyethers", J. Biomed. Res., 1990, 1397-1411, Vol. 24 Sono SCOTT-BURDEN et al., "Extracellular Matrix: Differential Influence on Growth and Biosynthesis Patterns of Vascular Smooth Muscle Cells from SHR and WKY Rats", J. Cell Physiol., 1989, 267-274, Vol. 141 SCOTT-BURDEN et al., "Genetically Engineered Smooth Muscle Cells as Linings to Improve the Biocompatibility of 52 Cardiovascular Prostheses", Circulation, 1996, Il235-238, Vol. 94 (9 Suppl.) SMITH et al., "Nitric Oxide-Releasing Polymers Containing the [N(O)NO] Group", J. Med. Chem., 1996, 1148-1156, Vol. 39 53 SPILIZEWSKI et al., "The Effect of Hydrocortisone Acetate Loaded Poly (DL-Lactide) Films on the Inflammatory Response", J. 54 Control, Rei., 1985, 197-203, Vol. 2 STUEHR et al., "Nitric Oxide - A Macrophage Product Responsible for Cytostasis and Respiratory Inhibition in Tumor Target 55 Cells", J. Exp. Med., 1989, 1543-1555, Vol. 169 WILLIAMS et al., 'Safety and Tolerability of Intravenous-to-Oral Treatment and Single-Dose Intravenous or Oral Prophylaxis 56 with Trovafloxacin", Am. J. Surg., 1998, 74S-79S, Vol. 176 WIEMAN et al., "Efficacy and Safety of a Topical Gel Formulation of Recombinant Human Platelet-Derived Growth Factor-BB 57 (Becaplermin) in Patients with Chronic Neuropathic Diabetic Ulcers", Diabetes Care, 1998, 822-827, Vol. 21 ZICHE et al., "Nitric Oxide Promotes DNA Synthesis and Cyclic GMP Formation in Endothelial Cells from Postcapillary 58 Venules", Biochem. Biophys. Res. Comm., 1993, 1198-1203, Vol. 192 Abstract, Derwent WPI, HU 9801673 A1 (08-28-2000), (Cycl-N) Cyclolab Ciklodextrin Kutato Fejleszto, 59

1

Examiner Signature	Let hole Bare	Date 3/17/04 Considered	

RECEIVED

JAN 1 2 2004

<sup>&</sup>lt;sup>1</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language translation is attached.